K040757

APR 13 2005

Implants from Implantologists

# K040757

## SIC *pro* Dental Implant System

## *510(K)*
## *SUMMARY OF SAFETY AND EFFECTIVENESS*

DATE: 2005-03-07


**Establishment:**
SIC invent AG
Birmannsgasse 3
Basel, SWITZERLAND 4055
Registration Number: 3004443656

**Owner/Operator:**
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Birmannsgasse 3
Basel, SWITZERLAND 4055
Owner/Operator Number: 9060857

**Official Correspondent:**
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## 1. Description of the Device

### 1.1. Device Name & Classification

| | |
|---|---|
| Common/Generic Device Name: | ENDOSSEOUS DENTAL IMPLANT, COMPONENTS & ACCESSORIES |
| Classification Name: | IMPLANT, ENDOSSEOUS, ROOT-FORM |
| Trade Name: | SIC *pro* System, Dental Implants & Accessories |
| Regulation Number: | 872.3640 |

### 1.2. Description of SIC *pro* System Implants

SIC *pro* System solid screw dental implants are root-form endosseous dental implant devices made out of grade 4 titanium according ASTM F 67. The implants are available in three different diameters (ø3.3 mm, ø4.2 mm, ø5.3 mm) and various length from 7.5 mm up to 16 mm. All ø3.3 mm diameter implants are cylindrical as well as the implants in diameter ø4.2 mm and ø5.3 mm in

length of 7.5mm. All other implants in diameter ø4.2 mm and ø5.3 mm are partly tapered. The anchorage surface is grit blasted and acid etched for faster osseointegration and secondary stability.

The face side of the implant has a hexagon drill hole and a standard screw thread to ensure a secure and anti-rotational connection of the congruent abutment and the implant. Throughout the different diameters the hexagon drill hole has identical measurements.

SIC *pro* System Implants are delivered single packed in combination with a implant cover screw and supplied in sterile condition (sterilized by gamma-radiation).

### 1.3. Description of SIC *pro* System Abutments & Accessories

SIC *pro* System Abutments & Accessories are various in shape, length and diameters and made out of three different materials (titanium grade 5, implant steel 316L, zirconium oxide). Through a hexagon socket and a vertical drill hole, the abutments can be connected with the implant secure and anti-rotational.

SIC *pro* System Abutments & Accessories are supplied single packed in non-sterile condition. These parts of the system are intended to be sterilized by the user by and have been validated by SIC using a standardized and validated steam (autoclave) sterilization process (15 min., 136°C, 3 bar).

## 2. Predicate Devices

- Straumann AG, ITI Dental Implant System®, K033984;
- FRIADENT GmbH, ANKYLOS® Dental Implant System, K040946;
- Nobel Biocare USA Inc., Nobel Biocare Endosseous Iplants, K041661;
- Straumann AG, 1.5mm synOcta Abutment, K022859;
- Friadent GmbH, XIVE® TG Abutment, K032302.

## 3. Indication for Use

The SIC *pro* System Dental Implant is a root form endosseous dental implant system that is indicated to be implanted in the upper and/or lower jaw arches. The implants may be used in combination with various SIC pro System Abutments for single or multiple unit prosthetic attachment to restore a patient's chewing function.

Patient's must be applicable for dental treatment with endosseous implants.

In cases where the ridge is too narrow to recieve a 4.2mm or 5.3mm diameter implant, the 3.3mm implant can be used. Under such conditions, we highly recommend the placement of additional fixtures to share the occlusal load of the prosthetic restoration.

The SIC pro System Abutment is intended to be placed into the SIC pro System Implant to provide a safe and effective fit of screw retained and/or cementable crowns and bridges.

## 4. Conclusions

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the SIC *pro* System Dental Implants, Abutments and Accessories are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2005

Mr. Georg Schilli
Official Correspondent
SIC Invent AG
Birmannsgasse 3
Basel, SWITZERLAND 4055

Re: K040757
Trade/Device Name: SIC pro System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: April 7, 2005
Received: April 11, 2005

Dear Mr. Schilli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): **K040757**

Device Name: **SIC *pro* System**

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Prescription Use __**YES**___ AND/OR Over-The-Counter Use __**NO**__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
510(k) Number: K040757